K113480

JAN 20 2012

510(k) Summary

Owner/Manufacturer:	CaridianBCT, Inc. 10811 W. Collins Avenue Lakewood, Colorado 80215
Contact Person:	Tina O'Brien Senior Regulatory Affairs Specialist Office Phone: (303) 239-2082
Summary Date:	November 18, 2011
Trade Name:	Spectra Optia® Apheresis System
Common Name:	Therapeutic Apheresis System
Classification Name:	Separator, Automated, Blood Cell and Plasma, Therapeutic
Product Code:	LKN
Predicate Device:	Spectra Optia Apheresis System

Device Description:

The Spectra Optia® Apheresis System is a centrifugal system that separates whole blood into its cellular and plasma components. The system is used therapeutically to remove and replace the removed plasma with healthy donor plasma (i.e. plasma exchange) from patients who suffer from adverse hematologic and other conditions.

The system includes a disposable Exchange Set through which the patient's blood passes, and a machine that controls the separation of blood and the removal and replacement of plasma. The Spectra Optia system's embedded software has been enhanced to reduce the likelihood of excessive platelet loss/removal during Therapeutic Plasma Exchange (TPE) procedures when there are repeated RBC spillover alerts and no remedial action is taken.

Intended Use:

The Spectra Optia® Apheresis System, a blood component separator, is intended for use in therapeutic plasma exchange.

Technological Comparison:

The base technology of the Spectra Optia system is not affected by this software change to minimize the potential for spillover conditions and to provide earlier detection and notification to the user of a potential platelet loss if appropriate action is not taken. There is no change to the disposable Exchange Set.

Discussion of Non-clinical Data:

The correct functioning of the software modifications was verified through the following activities:

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- **Reliability:** Reliability was assessed using tests to simulate expected usage profiles.

- **Usability:** Usability was verified with simulated use runs on the affected protocol.

- **Robustness:** Boundary condition testing was conducted to explore the software for expected behavior. Boundary conditions address critical values, maximum and minimum values, as well as values just inside/outside established boundaries.

- **Regression:** Specific regression testing was conducted related to the software updates for the platelet loss mitigation.

Discussion of Clinical Data:

Clinical validation data were not necessary, as the modifications did not impact the performance specifications of the system's therapeutic apheresis protocols.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Ms. Tina O'Brien
Senior Regulatory Affairs Specialist
Caridian BCT, Inc.
10810 West Collins Avenue
LAKEWOOD CO 80215

JAN 20 2012

Re: K113480
Trade/Device Name: Spectra Optia® Apheresis System
Regulation Number: None
Regulation Name: None
Regulatory Class: Unclassified
Product Code: LKN
Dated: December 21, 2011
Received: December 23, 2011

Dear Ms. O'Brien:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

4 Intended Use Statement

510(k) Number: K113480

Device Name: **Spectra Optia® Apheresis System**

Intended Use

The Spectra Optia® Apheresis System, a blood component separator, is intended for use in therapeutic plasma exchange.

Prescription Use: **YES** (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use: **NO** (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K113480